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**Drug Safety Communication: NSAIDs Increase Chance of Heart Attack or Stroke**

Non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used to treat pain and fever from a variety of medical conditions such as arthritis, menstrual cramps, headaches, colds, and the flu. NSAIDs are available by both prescription and over-the-counter. Examples of NSAIDs include ibuprofen, naproxen, diclofenac, and celecoxib.

The risk of heart attack and stroke with NSAIDs was first described in 2005 in the *Boxed Warning* and *Warnings and Precautions* sections of the prescription drug labels. Since then, the United States Food and Drug Administration (FDA) has continuously reviewed new safety information as it became available, including observational studies, a large combined analysis of clinical trials, and other scientific publications.

On July 9, 2015, the FDA announced they would be strengthening an existing label warning that NSAIDs increase the chance of a heart attack or stroke. Prescription labels for NSAIDs will be revised with the following information:

- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
- The risk appears greater at higher doses.
- It was previously thought that all NSAIDs may have a similar risk. Newer information makes it less clear that the risk for heart attack or stroke is similar for all NSAIDs. However, this newer information is not sufficient for the FDA to determine that the risk of any particular NSAID is definitely higher or lower than that of any other NSAID.
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.
- In general, patients with heart disease or risk factors for heart disease have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
- There is an increased risk of heart failure with NSAID use.

Patients taking NSAIDs should seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath or trouble breathing, weakness in one part or side of their body, or slurred speech.

For the full MedWatch safety alert, please refer to the "FDA Drug Safety Communication: FDA strengthens warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes" article found on the [FDA Drug Safety and Availability](#) Web page.